#### **REMARKS**

Reconsideration and withdrawal of the rejections of this application are requested in view of these remarks, which place the application in condition for allowance.

#### I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 80-105 are pending in this application.

No new matter is added.

## II. THE ART REJECTIONS ARE OVERCOME

Claims 80-105 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over JP 5-211852. The rejection is traversed.

Applicants respectfully provide the Examiner with a full English translation of JP 5-211852 which is being filed concurrently with this paper and provides a better indication of the content of the reference than the copy currently on file. Initially, Applicants kindly remind the Examiner that "[a] rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *In re Buszard* 504 F.3d 1364, 1366 (Fed. Cir. 2007) (citing *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001) ("Invalidity on the ground of 'anticipation' requires lack of novelty of the invention as claimed . . . that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim.")). With this in consideration, Applicants assert that the claimed invention is novel over JP 5-211852., as the cited reference fails to teach each and every limitation of claim 15.

JP 5-211852 does not disclose the production of any emulsifiers, let alone the first and second emulsifiers as currently claimed. The presence of water in the mixtures described in this document means that there will be no transesterification to produce the required emulsifiers and the lipase will hydrolyze the glycerides present in the oil resulting in the production of free fatty acids which are not emulsifiers. The present invention is further distinguished from the disclosure of JP 5-211852 as nothing in the reference relates to "a food material containing a

fatty acid ester and glycerol" as recited in claim 80. JP 5-211852 merely refers to the use of an oil which will not contain glycerol. A further point of distinction between the present invention and JP 5-211852 is that the reference does not disclose the inactivation or denaturation of the enzyme as required in step (b) of claim 80 as currently pending.

Therefore, JP 5-211852 does not teach each and every limitation of the claimed invention and hence the present invention is clearly novel over JP 5-211852.

Establishing a prima facie case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143. The Examiner is respectfully reminded that in order to ground an obviousness rejection, there must be some teaching which would have provided the necessary incentive or motivation for modifying the reference's teachings. In re Laskowski, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); In re Obukowitz, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). As stated by the Court in In re Fritch, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. In re Dow, 5 U.S.P.O.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Supreme Court has recently reaffirmed the factors set out in Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18: "[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727.

Applicants assert that JP 5-211852 relates to the addition of a lipase to a mixture of water and less than 30% oil in order to produce a low oil creamy substance.

Claim 80 as currently pending relates to:

"A method for preparing a foodstuff, wherein the foodstuff comprises a first emulsifier and a second emulsifier, the method comprising:

(a) contacting a food material containing a fatty acid ester and glycerol with an enzyme having esterase activity, such that a first emulsifier is generated by the enzyme from the fatty acid ester and a second emulsifier is generated by the enzyme from the glycerol; and (b) inactivating or denaturing the enzyme to *provide* the foodstuff comprising the emulsifiers, the fatty acid ester, and the enzyme in an inactive form or a denatured form."

There is no teaching whatsoever in JP 5-211852 which would motivate a person skilled in the art to arrive at the current invention. JP 5-211852 is directed towards producing a low oil content creamy substance from a mixture of oil and water, without requiring emulsifiers, stabilizers or thickeners. It is clear that in the presence of the water the lipase will not transesterify the glycerides to produce an emulsifier, but will hydrolyze them to produce free fatty acids which, as previously stated above, are not emulsifiers.

There is also no suggestion in JP 5-211852 that would motivate a skilled artisan to use a foodstuff containing a fatty acid ester and glycerol so as to produce first and second emulsifiers. Thus, JP 5-221852 does not teach step (a) of claim 80. JP 5-211852 is directed towards a low oil composition and would be no motivation to reduce the water content so as to result in transesterification of the fatty acid esters to result in the production of an emulsifier. Even if by chance the water content happened to be reduced, a person of ordinary skill in the art would not arrive at the present invention because the absence of the glycerol would mean that no second emulsifier, as required in the present invention would be produced. Therefore, emulsifier generation would not be inherent and/or obvious from the teaching of JP 5-211852 as alleged by the Examiner.

Reconsideration and withdrawal of the art rejections are requested.

# REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and the SPE, is respectfully requested. The Examiner is requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

# **CONCLUSION**

This application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

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(56)References

Japanese Unexamined Patent 2 - 200163 (JP, A)

(54) [Title of the Invention] A Production Method of a Low Oil Content Creamy Substance.

[Scope of the Claims of the Patent]

[Claim 1] A production method of a low oil content creamy substance with the special characteristic that a lipase agent (However not including spices) is added to a mixture of water and less than 30% oil which is then agitated.

[Claim 2] A production method of a low oil content creamy substance as stated in Claim 1 wherein the lipase agent is a micro - organism having lipase productivity.

[Claim 3] A production method of a low oil content creamy substance as stated in Claim 1 and Claim 2 wherein the lipase agent includes lipase with selectivity of 1<sup>st</sup> position and 3<sup>rd</sup> position glycerides.

[Claim 4] A production method of a low oil content creamy substance as stated in either of Claims  $1 \sim 3$  wherein the oil content is a liquid oil.

[Claim 5] A production method of a low oil content creamy substance as stated in either of Claims 1 ~ 4 wherein the aqueous solution with an oil content of less than 30% does not contain a emulsifier.

# [Detailed Description of the Invention] [0001]

[Field of Industrial Application] The present invention relates to a production method of a creamy substance with a low oil content and high stability which can not only be used in the field of food product production in the production of creamy food products such as fresh cream, mayonnaise, margarine and ice cream, etc., but can also be utilized extensively in the production of cosmetics, pharmaceuticals and other chemical products.

# [0002]

[Prior Art] In recent years, in the food production industry, in conjunction with consumer dietary diversification and heightened health consciousness, the demand for food products which are light and low in calories has increased.

# [0003]

Conventionally, for example, among cream types which use vegetable oils and fats, the combined use of sucrose fatty acid ester and lecithin has supported the contrasting properties of the said cream types, namely, foamability function and stability prior to whipping. However, in conventional cream types, in order to give an oiliness and richness of flavor, etc., normally an oil and fat percentage content in excess of a minimum of 40% is required, and this is a prime cause of the high calorific content of cream products.

# [0004]

Also, for example in Laid Open Patent Gazette No. Sho. 54 - 39459, in order to maintain the stability of emulsified products, casein salt and gum types, etc., are used, however, from the perspective of flavor, these additives can not be said to be desirable.

# [0005]

[Problems to be Solved by the Invention]

Beginning with the above examples, various emulsifier processing methods have until now been earnestly researched, however, a low oil content creamy substance which is satisfactory from all of the aspects of property of matter, stability and flavor has yet to be developed. Furthermore, in the production of the said creamy substance, normally, additives such as emulsifiers and stabilizers, etc., are required, and a creamy substance which does not use the above mentioned additives and has an

oil content of less than 30% and moreover has superior form retention and stability has yet to be produced.

[0006]

Therefore, the aim of the present invention is to develop a new and novel method of producing a low fat content creamy substance which has a low oil content and does not use emulsifiers, stabilizers and thickeners, etc., and has the characteristic of remaining stable for a long period and of having good form retention.

[0007]

[Means to Solve the Problems] In order to achieve the said aim, earnest research has been completed, and the resultant present invention is a production method of a low oil content creamy substance wherein the oil content is several % - 30% (percentage by weight, the same hereafter).

[8000]

That is to say, the present invention is a production method for a low oil content creamy substance which has the special characteristic that a lipase agent is added to a mixture consisting of less than 30% oil and water, which is then agitated. According to the present invention, it is possible to obtain a creamy substance by an extremely simple method whereby, to the mixture of several % ~ 30% oil and water, minute amounts of salt is added as required and 0.01 ~ several % of lipase agent is added and agitated gently for a period of between 30 minutes ~ several days at a temperature of 10 ~ 80°C, preferably at between room temperature and 70°C. The corresponding effect can not be obtained with the addition of more than several % of the lipase agent. Also, as the operation of the lipase agent is reduced when processed at temperatures of more than 80°C, this is therefore undesirable. Furthermore, as for the oil, in the case where it contains constituents with a high fusion point, it can be used by adding the lipase agent after cooling to below 80°C following heat fusion.

[0009]

The obtained creamy substance is in an emulsion state, and has extremely good form retention properties and will remain stable for a period of several months at a temperature of 4°C.

[0010]

The lipase agent used in the present invention can be of either a micro - organism, vegetable or animal source (However, excluding spices), for example, normally it is convenient to use products on the market such as Rhizopumdelemar, Mucor miche, Alcaligenes sp., etc., lipase of a micro - organism origin having selectivity of 1<sup>st</sup> position and 3<sup>rd</sup> position glyceride, Aspergillus alger, Candida cylindracea, Geotricum candidum., etc., so-called random type lipase of a micro - organism origin, lipase of a vegetable oil origin such as soy bean, rice bran and sun flower seed, etc., and animal pancreas lipase, etc. As for such lipase agents, apart from actual lipase, immobilized lipase obtained by an ion or covalent binding method, entrapment method, etc., and other common methods, in addition to, the micro - organism itself such as mold, yeast or bacteria, etc., which has the ability to produce the said lipase can be used to obtain the same creamy substance.

# [0011]

As for the oil, vegetable fats and oil, animal fat and oil, or synthetic oils can be used. As for animal and vegetable fats and oils, soy bean, rape seed oil, cotton seed oil, corn oil, safflower oil, sunflower oil, sesame seed oil, olive oil, linseed oil, castor oil, palm oil, coconut oil, —— oil, —— fat, cacao oil, illipe butter, Borneo taro oil, Chinese taro oil, beef tallow, lard, milk fat, fish oil, and squid oil, etc., or ester replacement oils and fats and wax types can be cited. As for synthetic oils, they can be suitably selected from the group of direct linked or side linked monoatomic or polyatomic carboxylic acid having a saturated or unsaturated bond formed from carbon numbers 2 ~ 24, and direct linked or side linked monoatomic or polyatomic alcohols and mono polyesters having a saturated or unsaturated bond formed from carbon numbers 1 ~ 24., for example, there is oleic acid methyl, myristic acid isopropyl, malic acid diisostearyl alcohol ester, 2 ethyl hexanoic acid triglyceride, octanoic acid or decanoic acid triglyceride, propylene glycol dibehenic acid, etc. Furthermore, the present invention is not limited to the examples given.

# [0012]

In the present invention, when producing the creamy substance, emulsifiers, stabilizers and thickeners are not necessary, and as for raw materials, only water or deionized water, oil and lipase agent are required. Furthermore, in order to achieve a creamy substance with further enhanced form retention, the addition of  $0.01 \sim 10\%$  preferably  $0.1 \sim 5\%$  of salt, for example calcium chloride, sodium chloride, etc., chlorides of  $1^{st}$  position through  $3^{rd}$  position monoatomic or tervalent metal ions, carbonate, lead nitrate, sulphate, etc., are effective.

## [0013]

By the aforesaid means, it is possible to produce a creamy substance which does not require stabilizers, thickeners and emulsifiers, has a low oil content of less than 30% and which is stable and has good form retention.

#### **[0014]**

## [Embodiments]

[Embodiment 1] To a mixture containing deionized water 100ml and palm oil 10g, 0.2ml of lipase derived from Mucor michel (Manufactured by Nobo Nordisk Japan (Ltd), product name "Parataze 1000") was added and left at room temperature for 1 hour after which it was agitated at 200 rpm using a homomixer. As a result, the said solution became creamy with good form retention and remained stable for a period of 3 months at 4°C without the oil and water separating.

#### [0015]

[Embodiment 2] To a mixture containing deionized water 100ml and rape seed oil 20g, 1ml of a 0.5mg/ml aqueous solution of lipase derived from Rhlzopus delemar (Manufactured by Tenno Pharmaceuticals (Ltd), product name "Lipase D") was added. In addition, 1% of each of potassium chloride and potassium carbonate is added and is agitated at a temperature of 37° by the same method as the first embodiment. The resultant creamy substance has both good form retention and flavor and is stable at 4°C for a period of 3 months.

#### [0016]

[Embodiment 3] To a mixture of tap water 100ml and lard 20g, 1% of each of calcium chloride and sodium chloride is added. 1ml of a 1mg/ml water soluble solution of lipase derived from pig pancreas (Manufactured by SIGMA, reagent) was added and agitated at a temperature of 40° by a homomixer for a period of 1.5 hours. The resultant creamy substance, as with the aforesaid embodiments, remained stable for a period of 3 months at 4°C.

#### [0017]

[Embodiment 4] To a mixture of deionized water 100ml, soybean oil 10g and yeast extract 1g, 1 platinum loop of lipase production fungus (Mucor cirinelloides IFO5398) was added and agitated at 250 rpm for a period of 4 days. As a result, it was possible to obtain a creamy substance with superior form retention.

#### [0018]

[Embodiment 5] Tap water 1 liter and behenic acid isostearyl alcohol ester 400g synthesized using a separate usual method and 10ml of a 0.5g/ml aqueous solution of lipase derived from Candida cylindracea (Manufactured by Meito Sangyo (Ltd), product name "Lipase OF") was used, and agitated the same as the first embodiment. The creamy substance resulting from this maintained its form for a period of 5 months at 4°C and remained stable without recognizable separation of the constituents.

#### [0019]

[Embodiment 6] Using the same ingredients as stated in the first embodiment, the mixture was agitated at 200 rpm for a period of 5 hours at 40°C while blowing in air. The resultant creamy substance had a soft whipped creamy feel, superior form retention and remained stable when kept for a period of 3 months at 4°C.

#### [0020]

[Embodiment 7] To a mixed solution of deionized water 100ml and triolein 20g, 0.2ml of lipase derived from Mucor mlehei (Manufactured by Nobo Nordisk Japan (Ltd), product name: "Parataze 1000") was added and agitated using the same method as the first embodiment at 40°C to obtain cold cream. The cold cream obtained was safe, spread easily and reacted well with the skin.

#### [0021]

[Effects of the Invention] By using the method of the present invention, it is possible to obtain by a simple operation a new creamy substance which does not require the addition of emulsifiers, stabilizers or thickeners, etc., has an oil content of less than 30%, has a good flavor, superior form retention and which is stable. By this means it is possible to produce low calorie food products containing oils and fats such as whipped cream, mayonnaise, margarine, etc., as well as cosmetics and pharmaceuticals.

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